



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/552,836

10/13/2005

Michael Forstner

TX/4-33176A

2236

75074

7590

01/26/2009

NOVARTIS INSTITUTES FOR BIOMEDICAL RESEARCH, INC.
400 TECHNOLOGY SQUARE
CAMBRIDGE, MA 02139

EXAMINER

WEN, SHARON X

ART UNIT

PAPER NUMBER

1644

MAIL DATE

DELIVERY MODE

01/26/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/552,836	Applicant(s) FORSTNER ET AL.	
	Examiner SHARON WEN	Art Unit 1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 October 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-8 is/are pending in the application.
- 4a) Of the above claim(s) 3 and 5-8 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 4 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's amendment, filed 10/28/2008, has been entered.
Claims 2 and 9-11 have been canceled.
Claims 1 and 3-8 are pending.
Claims 3 and 5-8 have been withdrawn from further consideration under 37 CFR § 1.142(b) as being drawn to non-elected Groups and/or Species.
Claim 4 is currently under examination as they read a pharmaceutical composition comprising an inhibitor of Vav1, wherein the elected inhibitor is a Vav1 binding antibody.
2. This Action will be in response to Applicant's Arguments/Remarks, filed 10/28/2008.
The rejections of record can be found in the previous Office Action.

Claim Rejections - 35 USC § 112, first paragraph

3. The previous written description rejection under 35 USC 112 first paragraph for the recitation of "inhibitor of Vav protein" has been withdrawn in view of Applicant's amendment, filed 10/28/2008.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claim 4 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Hilton et al. (US Patent 6,323,317) in view of Sepulveda et al. (The Journal of Biological Chemistry 2000, 275:14005-14008) for reasons of record.

Applicant's arguments, filed 10/28/2008, have been fully considered but have not been found convincing essentially for the reasons of record.

Applicant argues that the intended use for the claimed pharmaceutical composition is for treating graft rejection, inflammatory or autoimmune diseases is not obvious; there would be no motivation for the one skilled in the art to combine the Vav1 inhibitor with an immunosuppressant in a pharmaceutical composition.

In response to Applicant's argument, it is noted that the present claim is drawn to a pharmaceutical composition comprising a Vav1 binding antibody and at least one second agent. The claim does not recite the intended use noted by Applicant nor does the claim require the pharmaceutical composition to be used for treating graft rejection, inflammatory or autoimmune diseases. Therefore, Applicant's argument on the unexpected results on the intended usage of the pharmaceutical composition is not commensurate in scope with the claimed invention.

Furthermore, Applicant is reminded that "obviousness can be established for achieving the claimed product for different reasons and the prior art/examiner does not need to know all of the properties of the claimed invention" *In re Dillon*, 16 USPQ2d 1897 (Fed. Cir. 1990); however there must be some suggestion or motivation. Therefore, the reason or motivation to combine may often suggest doing what the inventor has done, but for a different purpose or to solve a different problem than that asserted by the inventor. See MPEP 2144.

The motivation was provided by Hilton in the teaching of a pharmaceutical composition comprising a Vav-1 inhibitor and a second agent (see column 30, second full paragraph, in particular, line 30). It is noted that, under the broadest reasonable interpretation, the various antibacterial or antifungal agents taught by Hilton read on the recited second agent, i.e., immunosuppressant, immunomodulatory or anti-inflammatory drug or a chemotherapeutic agent.

Given that Hilton taught a pharmaceutical composition comprising a Vav-1 inhibitor and a second agent and that Vav-1 binding antibodies were well known in the art at the time of the invention was made as evidenced by Sepulveda, it would have been obvious to one of ordinary skill in the art to make pharmaceutical composition comprising a Vav1 inhibitor as taught by Hilton wherein the inhibitor is an anti-Vav1 antibody as taught by Sepulveda because using antibodies as inhibitors in general were well established in the art.

Applicant's arguments have not been persuasive.

Therefore, the rejection of record is **maintained** for the reasons of record, as it applies to the amended and newly added claims. The rejection of record is incorporated by reference herein, as if reiterated in full.

Conclusion

6. No claim is allowed.

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHARON WEN whose telephone number is (571)270-3064. The examiner can normally be reached on Monday-Thursday, 8:30AM-6:00PM, ALT. Friday, EST.

Art Unit: 1644

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eileen O'Hara can be reached on (571)272-0878. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sharon Wen/

Examiner, Art Unit 1644

January 14, 2009

/Phillip Gambel/

Primary Examiner

Technology Center 1600

Art Unit 1644

January 21, 2009